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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/079,640	05/15/1998	HENRY DANIELL	922.6588P	8567

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EXAMINER	
FOX, DAVID T	
ART UNIT	**PAPER NUMBER**
1638	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/079,640	Daniell
Examiner	**Group Art Unit**
Fox	1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☑ Responsive to communication(s) filed on 12/16/03.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☑ Claim(s) 1, 3-96, 100-215 is/are pending in the application.

Of the above claim(s) 1-85, 100-106, 108-117, 120, 121, 123-167, 170, 177-188, 200-213 is/are withdrawn from consideration.

☑ Claim(s) 4-84, 86-96, 107, 118-119, 122, 168, 169, 172-176, 189, 194-195 is/are allowed.

☑ Claim(s) 3, 171, 190-193, 196-199, 214-215 is/are rejected.

☐ Claim(s)_____ is/are objected to.

☐ Claim(s)_____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on_____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on_____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number)_____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:_____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s)._____

☐ Interview Summary, PTO-413

☑ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other_____

Office Action Summary

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 December 2002 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The application should be reviewed for errors. Errors appear, for example, in claim 190, line 10, where "of" after "competent" should be deleted. The phrase should read --competent to-- rather than "competent of to".

The amendments of 16 December 2002 have obviated the rejections under 35 USC 112, second paragraph, of record; and the new matter rejection for claims 3, 171, 190, 191, 193 and 196-199. The obviousness-type double patenting rejection over application Serial No. 08/972,901 has been obviated by the abandonment of that application.

Claims 3, 171 and 190-192 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-23, 25-29, 31 and 34 of U.S. Patent No. 5,932,479, as stated on page 2 of the last Office action. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last office action.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's intent to file a Terminal Disclaimer is noted. The rejections will be maintained until receipt of a properly executed Terminal Disclaimer.

Claims 193 (newly amended) and 214-215 (newly submitted) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 193 is indefinite in its recitation of "in a" in the penultimate line, which is awkward and should be replaced with --into a--.

Claim 214 is indefinite in its recitation in the third line from the bottom of "which plant is the same as or different from the target higher plant", which appears to contradict the recitation in lines 7-8 that the flanking chloroplast DNA sequences are "from a plant species different from the target plant."

Claim 215 is indefinite for failing to further limit claim 214. The recitation of heterologous sequence coding for a selectable phenotype is found in the fifth and sixth lines from the bottom of claim 214.

Claim 192 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on page 3 in the last Office action for claims 3, 171, 190-193

and 196-199. Unlike the other claims previously included in this rejection, claim 192 has not been amended to remove the offending phrase "transcriptionally active polycistronic spacer region" which constitutes NEW MATTER.

Claims 3, 171, 190-192 and 196-199 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the intergenic spacer 2 region between the trnA and trnI genes of the chloroplast genome of higher plants, does not reasonably provide enablement for claims broadly drawn to the use of any intergenic spacer region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action on pages 3-4.

Claims 190-193 and 196-199 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the intergenic spacer 2 region between the trnA and trnI genes of the chloroplast genome of higher plants for the homologous recombination-mediated insertion of heterologous DNA into the intergenic spacer 2 region of the chloroplast genome of target higher plants, does not reasonably provide enablement for the insertion of heterologous DNA into any "transcriptionally active polycistronic spacer region" or "conserved transcriptionally active intergenic spacer region" of the chloroplast genome of a multitude of target higher plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is

most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action on page 4.

Claims 3, 171, 190-193 and 196-199 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any chloroplast vector comprising flanking chloroplast DNA sequences comprising portions of any "conserved transcriptionally active intergenic spacer region" or any "transcriptionally active polycistronic spacer region" of any sequence from any chloroplast genome of any plant species, and methods of their use to transform the chloroplasts of plants. In contrast, the specification only demonstrates flanking chloroplast DNA sequences comprising portions of the intergenic spacer 2 region between the trnA and trnI genes from tobacco. No guidance has been presented regarding the identification of any other "conserved" chloroplast DNA sequences from any other plant.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California* v. *Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that

material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Claim 192 remains rejected under 35 U.S.C. 102(b) as being anticipated by Zoubenko et al, as stated in the last office action on page 4.

Claim 192 remains rejected under 35 U.S.C. 102(b) as being anticipated by Staub et al (1993), as stated in the last office action on page 4.

Claims 3, 171 and 190-191 (amended) are rejected under 35 U.S.C. 102(b) as being anticipated by Staub et al (1995) in light of Sidorov et al (1999), as stated on pages 5-6 of the Office action of 20 November 2001 for claims 3, 171 and 190-192.

Claims 4-84, 86-96, 107, 118-119, 122, 168-169, 172-176, 189, 193-199 and 214-215 are free of the prior art, as stated in the last office action for claims 4-84, 86-96, 107, 118-119, 122, 168-169, 172-176, 189, and 193-199 on page 5.

Claims 4-84, 86-96, 107, 118-119, 122, 168-169, 172-176, 189 and 194-195 remain allowed, as stated on page 5 of the last Office action.

Applicant's arguments filed 16 December 2002 have been fully considered but they are not persuasive, insofar as they pertain to the rejections above.

Applicant urges that the enablement rejections are improper, given the instructions in the specification for the identification of other conserved spacer regions and the disclosure of chloroplast genome sequences by other workers including Sidorov et al and Ruf et al previously submitted by Applicant, as well as Sugita et al newly submitted by Applicant. The Examiner maintains that it is unclear whether other such polycistronic transcriptionally active spacer regions are conserved or exist in other chloroplast genomes, as admitted by Applicant on page 9 of the amendment of 16 December 2002, penultimate paragraph . It is also noted that Sidorov et al and Ruf et al are drawn to transcriptionally *silent* intergenic regions, as admitted by Applicant (see, e.g., page 9 of the amendment of 16 December 2002, penultimate paragraph), so that their relevance to the claimed invention is unclear. No particular region of the exemplified spacer region has been identified which is conserved among its class, which could be used as a probe. In the absence of such information, the skilled artisan would be forced to resort to an infinite number of trial-and-error experiments in an effort to identify even one other possible successful event. Such experimentation is undue. Applicant is also directed to Maier et al appended to the amendment of 28 March 2002, which demonstrates that chloroplast genomic regions are not all conserved among all higher plants (see, e.g., page 13 of the amendment of 28 March 2002).

Applicant urges that the art rejection over Zoubenko et al is improper, given the teaching by that reference that the trnV-rps12/7 spacer region is unique to the tobacco chloroplast genome,

rather than "conserved in all higher plants" as claimed. The Examiner responds that the reference merely teaches that two ORFs within that spacer, namely ORF131 and ORF70B, are unique to tobacco. The reference does not teach that other sequences within that spacer region are unique to tobacco, wherein said other regions could be used to provide the flanking regions of the claimed construct. The claims are not limited to a spacer region which comprises both ORF131 and ORF70B from tobacco.

Applicant urges that the art rejection over Staub et al (1993) is improper, given the failure of the reference to teach flanking sequences from a target plant species different from the species into which the vector was inserted, and the failure of the reference to teach that the flanking sequences are obtained from a conserved region. The Examiner maintains that the rejected claim is a product claim, wherein the identity of the target plant species is merely an intended use, as stated previously. The vector taught by Staub et al (1993) could be used to transform a target plant other than tobacco. Intended use is not given patentable weight in product claims, per MPEP 2111.02, *Pitney Bowes, Inc. V. Hewlett-Packard Co.*, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999), *Rowe v. Dror,* 42 USPQ2d 1550, 1553 (Fed. Cir. 1997), and *In re Schreiber,* 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The flanking sequences of the reference appear to have been from a conserved region, in the absence of evidence to the contrary. It is noted that claim 192 has not been amended to insert the phrase "conserved transcriptionally active intergenic spacer region".

Applicant urges that the newly reinstated art rejection is improper, given the later publication date of Sidorov et al which disqualifies it as prior art, and the failure of Sidorov et al

to teach the insertion of the flanking sequences into conserved intergenic spacer regions. The Examiner maintains that the Sidorov et al reference was cited to show an inherent property of the Staub et al (1995) reference, wherein the citation of such a reference illustrating a universal fact does not need to antedate Applicant's invention, per MPEP 2124 and 2131.01, part (III). Regarding the insertion into a conserved region, the Examiner maintains that Staub et al (1995) teach such a region comprising the intergenic spacer region between the universally present *rbcL* and *accD* chloroplast genes, as stated in the Office action of 20 November 2001.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

March 3, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638